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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,694	NAJAFI ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,33-59,64 and 69-72* is/are rejected.

7)☒ Claim(s) *31,32,60-63 and 65-68* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the expandable tine in claims 47 and 55, and the embodiment of claims 61-63 and 65-68 having both a readout device comprising a coil allowing electromagnetic telecommunication and wireless powering and a separate external reader for transmitting power or receiving data must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification lacks sufficient antecedent basis for the embodiment of claims 61-63 and 65-68 having both a readout device comprising a coil allowing electromagnetic telecommunication and wireless powering and a separate external reader for transmitting power or receiving data. The specification describes an embodiment on p. 11 wherein data may be transmitted to a pacing/ICD unit and/or an external reader, but such an embodiment lacks a separate non-implantable readout device comprising an inductor coil for electromagnetic telecommunication and powering, as claimed.

Claim Objections

Claims 1-4, 8-10, 13, 23, 24, 29, 30, 41, 44, 42, 45, 47, 49, 52, 53, 55 59, 63, 64, 68, 69, 70, and 72 are objected to because of the following informalities:

On line 3 of claim 1, line 5 of claim 1, line 3 of claim 2, line 5 of claim 2, line 1 of claim 3, line 1 of claim 4, each instance of "comprising of" should be replaced with "comprising";

On line 1 of each of claims 3 and 4, "the at least one sensor of " should be inserted before " the implantable sensing device";

On line 1 of claim 9, "physiological parameters include pressure" should be replaced with "one or more physiological parameters includes pressure";

On line 1 of claim 10, "one or more" should be inserted before "physiological parameters";

On line 1 of claim 11, "the" should be inserted before "one or more sensing devices";

On line 1 of claim 13, "the" should be inserted before "one or more sensing devices" and "are measuring" should be replaced with "measure(s)";

On line 1 of each of claims 23 and 24, "physiologic parameter" should be replaced with "one or more physiologic parameters";

On line 16 of each of claims 29 and 30, "diagnostic systems" should be replaced with "diagnosis";

On lines 1-2 of claim 41, "anchoring mechanisms" should be replaced with "an anchoring mechanism";

On line 2 of each of claims 41 and 42, "those used in" should be deleted;

On line 1 of each of claims 44 and 52, "method" should be replaced with "mechanism";

On line 2 of each of claims 44 and 52, "devices, wherein" should be replaced with "devices and wherein";

Also on line 2 of each of claims 44 and 52, commas should surround the phrase "one on each side";

On line 1 of each of claims 45 and 53, "the larger" should be replaced with "a larger";

On line 2 of each of claims 45 and 53, "the smaller" should be replaced with " a smaller";

On line 2 of each or claims 47 and 55, "tribeculated" should be replaced with "trabeculated";

On lines 1-2 of claim 49, anchoring schemes" should be replaced with "an anchoring mechanism";

On line 2 of claim 59, "said sensor data" should be replaced with "data from the sensor";

On line 1 of each of claims 63 and 68, "perform" should be replaced with "performs";

On line 2 of claim 64, "said sensor data" should be replaced with "data from said sensor";

On line 2 of each of claims 69 and 72, "coatings" should be replaced with "coating";

On line 1 of each of clams 70 and 72, "materials include but are" should be replaced with "material includes but is". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25, 26, 42, 43, 45, 47, 50, 51, and 53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 25

and 26 each recite the limitation "wherein the location of the ... sensing device is one or more" body part. Each f claims 42 and 50 recites, " an anchor that passes through a septum wall and opens on one or both sides of a septal wall, clamping said implantable device to the wall". Each of claims 43 and 51 recites, "an anchor that passes through the atrial septum". Each of claims 45 and 53 recites that a larger portion of the devices "is located in the right side of the heart and the smaller portion . . . is located in the left side". Claim 47 recites the limitation "a tine that catches on a tribeculated area of the heart".

However the body and its parts are considered non-statutory subject matter and cannot positively be claimed.

To overcome this limitation, lines 1-2 of claim 25, for example, should be replaced with "The system of claim 1, wherein the one or more implantable sensing devices are adapted to be located in one or more of the following areas:".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last line of claim 53 appears to be unfinished. The line reads, "device is located in the lefts side and includes at minimum". However, since the line is unfinished

it is impossible to understand what the device includes "at minimum" and therefore impossible to determine the scope of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> Or
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-11, 13, 15, 16, 19, 20, 23-30, 37-46, 48-54, 56-58, and 69-72 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent NO. 6,636,769 to Govari et al. Govari teaches a system for monitoring one or more physiological parameters for diagnosis or treatment of congestive heart failure (CHF) within a patient (col. 5, lines 39-47; col. 10, lines 1-55 of Govari). The system comprises at least one implantable sensing device 50, having at least one inductor coil 68 with optional electronics 52, 90, 100 (figs. 1 & 5; col. 5, lines 44-47; col. 6, lines 22-30; col. 6, line 66-col. 7, line 21 of Govari), and a non-implantable readout device 140, having at least one inductor coil 162 allowing electromagnetic telecommunication and electromagnetic wireless powering (fig. 8; col. 7, line 58-col. 8, line 5; col. 8, lines 33-65 of Govari).

Regarding claims 5-8, the sensing device 50 includes a battery, wherein the charge capacitor 114 acts as a batter (col. 7, line 48-col. 8, line 5 of Govari). With further regard to claims 6 and 8, the battery or charge capacitor 114 is rechargeable using wireless means (col. 7, line 48-col. 8, line 5 of Govari).

Regarding claims 9-11, 13, 23, and 24, the sensor 50 may sense pressure (col. 6, lines 5-14; col. 9, lines 17-40; col. 10, lines 50-60 of Govari). With further regard to claims 11 and 13, the sensor 50 may measure any left ventricular, left atrial, right ventricular, or right atrial pressure (col. 10, lines 50-60 of Govari).

Regarding claims 15, 16, 27, and 28 the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Govari teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Govari may certainly be used to determine drug treatment for a patient or for disease management, for example.

Regarding claims 19 and 20, a passive scheme is used (col. 8, lines 38-46 of Govari).

Regarding claims 25 and 26, the device may be located at the atrial septum, left or right atrium, or left or right ventricle of the heart (figs. 10 & 11; col. 10,lines 50-67 of Govari).

Regarding claims 29 and 30, the readout device 140 is capable of performing remote monitoring of congestive heart failure patients or of portable or ambulatory monitoring or diagnosis (col. 10, lines 2-67 of Govari).

Regarding claims 37-40, the implantable device 50 is capable of being implanted using a minimally invasive outpatient technique or catheter delivery method (cols. 11 and 12 of Govari).

Regarding claims 41-46, 48-54 and 56, the implantable device 50 uses an anchoring mechanism including a septal occluding device, a screw, or a tine (figs. 1, 3, 4, and 11; col. 6, lines 39-65; col. 10, lines 59-60 of Govari). With further regard to claims 42-45 and 50-53, the anchor passes through a septum wall and opens on one side of the wall, clamping the device to the wall (fig. 11; col. 10, lines 59-60 of Govari). With further regard to claims 44 and 52, the anchoring mechanism utilizes two umbrella shaped anchors 64, one on each side, which anchor the sensing device 50 (fig. 11 of Govari). With further regard to claims 45 and 53, a larger portion of the implantable device 50 is located on the right side of the heart while a smaller portion is located in the left side of the heart (fig. 11 of Govari). With further regard to claims 46 and 54, the anchoring mechanism is a helical screw (fig. 3 of Govari). With further regard to claims 48 and 56, the anchoring mechanism is made from nitinol (col. 6, lines 43-45 of Govari).

As to the language "in order to minimize the risk of thrombogenicity" in claim 45, the applicants should note that this is merely "results" language which cannot be relied upon to define over the prior art, since Govari teaches all of the claimed structural elements and their recited elements. Since the structure of the device of Govari is the same as that claimed, it is assumed that the claimed minimal risk of thrombogenicity will also result from the structure of Govari. If such is not the case, then the applicants have

failed to claim an essential element of the invention (i.e. a problem under 35 U.S.C. 112, 2nd paragraph).

Regarding claims 57 and 58, the implantable sensing device 50 is augmented with a radiation emitting source 100 (fig. 6A & B; col. 7, lines 15-17 of Govari).

Regarding claims 69-72, at least a portion of the implantable sensing device 50 is coated with one or more layers of thin coating 52 (fig. 5; col. 5, lines 49-51 of Govari), wherein the coating comprises titanium and polysilicon.

Claims 1-4, 9-11, 13, 15-20, 23-30, and 33-40 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,026,276 to Chubbuck. Chubbuck discloses a system for monitoring at least one physiological parameter, the system comprising at least one implantable sensing device 10, 38 and at least one non-implantable readout device 18, 20 (figs. 1, 11; col. 4, lines 25-45 of Chubbuck). The implantable device 10, 38, comprises at least one inductor coil 36 (fig. 4; col. 5, lines 32-56 of Chubbuck) and at least one sensor 28, 30 (figs. 3 & 4; col. 5, lines 3-55 of Chubbuck). The readout device 18, 20 comprises at least one inductor coil 83 allowing electromagnetic telecommunication and powering (figs. 1 & 11; col. 9, lines 43-53; col. 12, lines 1-11; col. 12, line 57-col. 13, line 17 of Chubbuck).

As to the language "for monitoring . . . for diagnosis of congestive heart failure" on lines 1-2 of claim 1 and "for monitoring . . . for treatment of congestive heart failure" on lines 1-2 of claim 2, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Chubbuck

teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Chubbuck is fully capable of being used for either diagnosis or treatment of congestive heart failure in a patient.

Regarding claims 3 and 4, the sensing device comprise at least one a capacitive sensor (col. 5, lines 47-56 of Chubbuck).

Regarding claims 9-11, 13, 15, 16, 25-28, and 37-40, the system monitors pressure (col. 4, lines 39-42 of Chubbuck). As to the types of pressures listed in claims 11 and 13, the type of pressure sensed is a result of the placement of the implantable sensing device. Both the type of pressure sensed in claims 11 and 13 and where, in a patient's body, the implantable sensing device is placed, as recited in claims 25 and 26, are merely "intended use" language which cannot be relied upon to define over the prior art, since Chubbuck teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Chubbuck is fully capable of being used in the heart or circulatory system such that any one of the listed pressures may be sensed. Similarly, regarding claims 15, 16, 27, and 28, the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Chubbuck teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Chubbuck may certainly be used to determine drug treatment for a patient or for disease management, for example. With regard to claims 37-40, as above, the method by which the implantable device is implanted in a body is further considered "intended use" language since it merely describes how the implantable device is used. Chubbuck

teaches all of the other claimed elements and their recited relationships, and the implantable device of Chubbuck may certainly be implanted using a minimally invasive outpatient technique or a catheter delivery method.

Regarding claims 17-20, a resonant, passive scheme is used (col. 5, line 35 of Chubbuck).

Regarding claims 23, 24, pressure is measured (col. 4, lines 25-43; col. 5, lines 32-56 of Chubbuck).

Regarding claims 29 and 30, the readout device 18, 20 is capable of performing portable or ambulatory monitoring.

Regarding claims 33-36, the readout device 18, 20 includes a barometric pressure sensor, wherein the barometric pressure sensor is used to compensate for variations in atmospheric pressure (col. 15, lines 15-34 of Chubbuck).

Claims 1, 2, 9-16, 19, 20, 23-30, 37-41, 43, 45-47, 49, 51, 53-55, 57-59, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,409,674 to Brockway et al. Brockway describes a system for monitoring at least one physiological parameter, the system comprising at least one implantable device 105 and at least one non-implantable readout device 140 (figs. 1, 2, 4, and 5 of Brockway). The implantable device 105 includes at least one coil and at least one sensor 305 (col. 8, lines 13-15; col. 10, lines 15-25 of Brockway). The readout device 140 comprises at least one inductor coil allowing electromagnetic telecommunication and powering (col. 7, lines 42-55; col. 10, lines 15-25 of Brockway). As to the language "for

monitoring . . . for diagnosis of congestive heart failure" on lines 1-2 of claim 1 and "for monitoring . . . for treatment of congestive heart failure" on lines 1-2 of claim 2, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Brockway teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Brockway is fully capable of being used for either diagnosis or treatment of congestive heart failure in a patient (col. 1, lines 38-60 of Brockway).

Regarding claims 9-14, and 23-26 the system is for monitoring pressure, wherein the pressure transducer 305 may be placed in any one of the chambers of the heart and therefore may measure any right or left atrial or ventricular pressure (col. 7, lines 14-37 of Brockway). With further regard to claims 12 and 14, the system calculates the change of pressure over time (dp/dt) (col. 1, lines 30-55; col. 9, lines 33-41 of Brockway).

Regarding claims 15, 16, 27, and 28 the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Brockway teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Brockway may certainly be used to determine drug treatment for a patient or for disease management, for example

Regarding claims 19 and 20, a passive scheme is used (col. 10, lines 15-25 of Brockway).

Regarding claims 27 and 28, the system may be used for disease management or pacing adjustments, for example (col. 11, lines 35-62; col. 14, lines 37-40 of Brockway).

Regarding claims 29 and 30, the readout device 140 is capable of closed-loop pacemaker parameter tuning to treat CHF or CHF related conditions, portable or ambulatory monitoring, data storage, and communication with other medical devices, including pacemakers, for example (figs. 1, 2, 4, and 5; col. 11, lines 14-62; col. 14, lines 30-40 of Brockway).

Regarding claims 37-40, the implantable device 105 is implanted using a minimally invasive outpatient technique or catheter delivery method (col. 1, line 65-col. 1, line27; col. 12, line 56-col. 13, line 17 of Brockway).

Regarding claims 41, 43, 45-47, 49, 51, and 53-55 the implantable sensing device 105 uses an anchoring mechanism including a screw 312A, tine 312B, 312D, or stent 312C (figs. 3A-D; col. 8, lines 26-52 of Brockway). With further regard to claims 43, 45, 51, and 53, the anchor 312A, 312B is capable of passing through an atrial septum. With further regard to claims 45 and 53, a larger portion of the implantable device 105 is capable of being located in the right side of the heart while a smaller portion of the device 105 is capable of being located in the left side of the heart. With further regard to claims 46 and 54, the anchoring mechanism is a helical screw 312A (fig. 3A of Brockway). With further regard to claims 47 and 55, the anchoring mechanism is a tine 312D that expands (figs. 3D and 7; col. 8, lines 45-52; col. 13, lines 43-47 of Brockway), wherein the expandable tine 312D is capable of catching on a trabecular area of the heart.

Regarding claims 57 and 58, the implantable sensing device 105 is augmented with a pacing stimulator or defibrillator 400, for example (figs. 4 & 5; col. 11, lines 14-62 of Brockway).

Regarding claims 59 and 64, the system is part of a closed-loop pacing/ICD tuning mechanism where the data from the sensor 305 is sent to a patient pacemaker for tailoring of pacing/ICD function (figs. 4 & 5; col. 11, lines 14-62 of Brockway).

Claims 1, 2, 5-11, 13, 15, 16, 19-30, 37-41, 48, 49, 56, and 69-72 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,231,516 to Kellman et al. Kellman discloses a system for monitoring at least one physiological parameter comprising at least one implantable sensing device 30, 44-46 and a non-implantable readout device 90, 100, 101 (figs. 7, 8, and 12 of Kellman). The implantable device 30, 44-46 comprises at least one inductor coil 30, 30A and at least one sensor 44-46 (figs. 1 & 2; col. 7, lines 40-56; col. 9, lines 23-25 of Kellman). The readout device 90, 100, 101 comprises at least one inductor coil 90 allowing electromagnetic telecommunication and electromagnetic wireless powering (figs. 7, 8, and 12; col. 13, lines 14-22 of Kellman).

Regarding claims 5-8, the implantable device 30, 44-46 includes a battery which is rechargeable using wireless means (col. 8, lines 20-39 of Kellman).

Regarding claims 9-11, 13, and 23-26, the system may monitor pressure, and the implantable device may be placed in any blood vessel of the body, including the aorta or pulmonary artery, such that any left or right atrial or ventricular pressure may be sensed (col. 6, lines 1-54; col. 9, lines 24-26 of Kellman).

Regarding claims 15, 16, 27, 28, and 37-40 the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Kellman teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Kellman may certainly be used to determine drug treatment for a patient or for disease management, for example. With regard to claims 37-40, as above, the method by which the implantable device is implanted in a body is further considered "intended use" language since it merely describes how the implantable device is used. Kellman teaches all of the other claimed elements and their recited relationships, and the implantable device of Kellman may certainly be implanted using a minimally invasive outpatient technique or a catheter delivery method.

Regarding claims 19-22, a passive or active scheme may be used (col. 8, lines 20-39; col. 13, lines 54-65 of Kellman).

Regarding claims 29 and 30, the readout device 90, 101 is capable of battery-operation capability (figs. 7, 8, and 12; col. 8, lines 20-39 of Kellman).

Regarding claims 41, 48, 49, and 56 the implantable device 30, 44-46 uses a stent 106 as an anchoring mechanism (fig. 7; col. 5, line 64-col. 6, line 5; col. 15, lines 42-60 of Kellman). With further regard to claims 48 and 56, the anchoring mechanism is made from nitinol or stainless steel (col. 38, line 65-col. 39, line 39 of Kellman).

Regarding claims 69-72, at least a portion of the implantable device is coated with at least one layer of thin coating, wherein the coating is parylene (col. 27, lines 25-32 of Kellman)

Allowable Subject Matter

Claims 31, 32, 60-63, and 65-68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claims 31 and 32, the prior art of record fails to teach or fairly suggest a system for monitoring at least one physiological parameter for diagnosis or treatment of congestive heart failure within a patient comprising an implantable sensing device, having a sensor and an inductor coil, and a non-implantable readout device, wherein the system is incorporated into a closed-loop system with a left atrium to right atrium unidirectional valve for preventing the development of pulmonary edema, in combination with all of the other limitations of the claims.

With regard to claims 60 and 65, the prior art of record fails to teach or fairly suggest a system for monitoring at least one physiological parameter for diagnosis or treatment of congestive heart failure within a patient wherein the system is part of a closed-loop pacing/ICD tuning mechanism and the sensor of the implantable sensing device is directly interrogated by the pacing/ICD unit, in combination with the non-implanted readout device having an inductor coil for electromagnetic powering and telecommunication and all of the other limitations of the claims.

With regard to claims 61-63 and 66-68, the prior art of record fails to teach or fairly suggest a system for monitoring at least one physiological parameter for diagnosis or treatment of congestive heart failure within a patient wherein the system is part of a closed-loop pacing/ICD tuning mechanism, and the system comprises both a non-implantable readout unit with an inductor coil for electromagnetic powering and telecommunication and a separate external unit for either the sole purpose of transmitting power to the sensor or receiving data from the sensor, in combination with all of the other limitations of the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,855,115 to Fonseca et al.

US Patent No. 6,631,296 to Parramon et al.

US Patent No. 6,400,990 to Silvian

US Patent No. 6,295,466 to Ishikawa et al.

US Patent No. 6,015,86 to Kensey et al.

US Patent No. 4,925,443 to Heilman et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

ROBERT L. NASSER
PRIMARY EXAMINER